### NATIONAL HEALTH SERVICE ACT 2006

# The Pharmaceutical Services (Fees for Applications) Directions 2013

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 131(1) and (2)(a), 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

The Secretary of State has consulted, in accordance with section 131(3)(a) of that Act, with such organisations as the Secretary of State considers appropriate that appear to the Secretary of State to represent persons providing pharmaceutical services.

#### Citation, commencement and application

**1.**—(1) These Directions may be cited as the Pharmaceutical Services (Fees for Applications) Directions 2013 and come into force on 1st April 2013.

(2) These Directions apply in relation to England.

#### Interpretation

**2.**—(1) In these Directions—

"the 2005 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005(**b**), as in force on 31st August 2012;

"the 2008 Directions" means the National Health Service Pharmaceutical Services (Fees for Applications) Directions 2008(c), as in force on 31st August 2012;

"the 2012 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2012(**d**), as in force on 31st March 2013;

"the 2012 Directions" means the Pharmaceutical Services (Fees for Applications) Directions 2012(e), as in force on 31st March 2013; and

"the 2013 Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(f).

(2) Words and expressions used in these Directions and in the 2013 Regulations bear the meanings they bear in the 2013 Regulations.

(3) Where reference is made in these Directions to a numbered regulation or Schedule, unless the context otherwise requires, it is to the regulation of or Schedule to the 2013 Regulations bearing that number.

<sup>(</sup>a) 2006 c. 41; section 131 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 68.

<sup>(</sup>b) S.I. 2005/641. These Regulations, and the amendments to them, were revoked by S.I. 2012/1909.

<sup>(</sup>c) Signed on 26th March 2008 and amended by the National Health Service Pharmaceutical Services (Fees for Applications) (Amendment) Directions 2008, signed on 17th April 2008.

<sup>(</sup>d) S.I. 2012/1909. These Regulations, and the amendments to them, were revoked by S.I. 2013/349.

<sup>(</sup>e) Signed on 20th July 2012.

<sup>(</sup>f) S.I. 2013/349.

#### Fees

**3.**—(1) The NHSCB must charge the specified fee to each person who makes a routine or excepted application, except that—

- (a) the fee may be waived in a case where the NHSCB has invited that person to make that application; and
- (b) no fee is payable in respect of an application under—
  - (i) regulation 27 (application for temporary listings arising out of suspensions),
  - (ii) regulation 28 (applications from persons exercising a right of return to a pharmaceutical list), or
  - (iii) regulation 29 (temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists).
- (2) Except where paragraph (3) or (4) applies, the specified fee is—
  - (a) in the case of a routine application,  $\pounds750$ ; or
  - (b) in the case of an excepted application—
    - (i) under regulation 23 (applications from NHS chemists in respect of providing directed services) in respect of enhanced services(a), £100,
    - (ii) under regulation 24 (relocations that do not result in significant change to pharmaceutical services provision), £250,
    - (iii) under regulation 25 (distance selling premises applications), £750,
    - (iv) under regulation 26(1) (change of ownership applications which are not combined with relocations)—
      - (aa) if the applicant is already included in a pharmaceutical list in respect of other premises, £150, or
      - (bb) if the applicant is not already included in a pharmaceutical list in respect of other premises, £250, or
    - (v) under regulation 26(2)) (change of ownership applications which are combined with relocations)—
      - (aa) if the applicant is already included in a pharmaceutical list in respect of other premises, £250, or
      - (bb) if the applicant is not already included in a pharmaceutical list in respect of other premises, £350.

(3) In the case of a routine application, or an excepted application of a type mentioned in paragraph (2)(b)(iii), if an earlier application (A1) before that application (A2)—

- (a) was of the same type as A2 (whether submitted under the 2005 Regulations, the 2012 Regulations or the 2013 Regulations); and
- (b) contained information relating to-
  - (i) the type of application,
  - (ii) the premises and opening hours, and
  - (iii) the provision of pharmaceutical services or directed services,

which is the same or similar to the information contained in A2,

and the proceedings relating to A1 reached their final outcome within 180 days of the submission to the NHSCB of A2, the specified fee for A2 is  $\pm 1,500$ .

(4) In the case of a routine application, or an excepted application of a type mentioned in paragraph (2)(b)(iii), if an earlier application (A2) before that application (A3)—

<sup>(</sup>a) Arrangements to provide advanced services proceed pursuant to notifications rather than applications.

- (a) was of the same type as A3 (whether submitted under the 2012 Regulations or the 2013 Regulations);
- (b) contained information relating to-
  - (i) the type of application,
  - (ii) the premises and opening hours, and
  - (iii) the provision of pharmaceutical services or directed services,

which is the same or similar to the information contained in A3; and

(c) was an application in respect of which the specified fee under this direction was £1,500 or £3,000,

and the proceedings relating to A2 reached their final outcome within 180 days of the submission to the NHSCB of A3, the specified fee for A3 is  $\pm 3,000$ .

(5) For the purposes of paragraphs (3) and (4)—

- (a) information relating to premises is similar if the premises in question are located in the same locality (having regard to how different localities have been identified in the relevant pharmaceutical needs assessment); and
- (b) information contained in an earlier application is not similar to information contained in the later application if the later application—
  - (i) is to address and does address the reasons the NHSCB or a Primary Care Trust (or on appeal, the Secretary of State) had for refusing the earlier application, or
  - (ii) follows an earlier application that was treated as withdrawn by virtue of-
    - (aa) paragraph 11 or 12 of Schedule 2 (Applications in respect of pharmaceutical lists and the procedures to be followed relevant information and documentation, and failure to provide undertakings), or
    - (bb) paragraph 11 or 12 of Schedule 2 of the 2012 Regulations (Applications in respect of pharmaceutical lists and the procedures to be followed relevant information and documentation, and failure to provide undertakings),

and the later application includes the missing information, documentation or undertakings the lack of which caused the earlier application to be treated as withdrawn.

#### Validity of applications where a fee is payable

**4.** Where the NHSCB charges a fee in relation to an application by virtue of these Directions, that application is only valid if that fee has been paid(a).

#### **Revocation and savings**

5.—(1) The Pharmaceutical Services (Fees for Applications) Directions 2012 are revoked.

(2) Where, by virtue of Schedule 9, the NHSCB is required to consider an application in accordance with—

- (a) the 2005 Regulations on or after 1st April 2013 in respect of which, immediately before 1st April 2013, a fee was payable under the 2008 Directions (by virtue of direction 5(2) of the 2012 Directions)—
  - (i) that fee is the specified fee in relation to that application (whether that application is submitted before, on or after 1st April 2013), and
  - (ii) the 2008 Directions apply in relation to that application; or

<sup>(</sup>a) If a fee, or any part of a fee, that is payable in relation to an application is missing, by virtue of paragraph 12(1)(b) of Schedule 2 to S.I. 2013/349, the NHSCB is required to request that the applicant provides the fee, or the missing part of the fee, within a specified period. If the applicant fails to comply with such a request within a period that has been reasonably specified by the NHSCB, by virtue of paragraph 12(2) of that Schedule, the application is to be treated as withdrawn.

- (b) the 2012 Regulations on or after 1st April 2013 in respect of which, immediately before 1st April 2013, a fee was payable under the 2012 Directions—
  - (i) that fee is the specified fee in relation to that application (whether that application is submitted before, on or after 1st April 2013), and
  - (ii) the 2012 Directions apply in relation to that application.
- (3) The continuity principles apply for the purposes of this direction, but as if—
  - (a) the 2008 Directions were provisions of the 2005 Regulations; and
  - (b) the 2012 Directions were provisions of the 2012 Regulations.

Signed by authority of the Secretary of State for Health

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Jeannette Howe Head of Pharmacy Department of Health

13th March 2013